

OCT 17 2008

Atty Dkt. No.: GHDX-005
USSN: 10/714,195**I. AMENDMENTS****IN THE CLAIMS**

Cancel claims 56, 63 and 65 without prejudice to renewal. Claims 40 and 64 have been withdrawn. Please enter the amendments to claims 31, 38, 60, and 62, as shown below.

1-30 (Canceled)

31. (Currently amended) A method for predicting the likelihood that a human colon cancer patient will ~~respond~~ exhibit a clinically beneficial patient response to treatment with an ErbB1 inhibitor, the method comprising:

a) assaying a normalized level of a predictive RNA transcript in a sample comprising ErbB1-expressing colon cancer cells obtained from said patient, wherein the predictive RNA transcript is the transcript of laminin gamma 2 (LAMC2); and

b) analyzing the normalized level of the LAMC2 transcript; and

c) predicting so as to predict the likelihood of response of the patient to treatment with an ErbB1 inhibitor based on the normalized level of the LAMC2 transcript, wherein the normalized level of LAMC2 RNA transcript correlates with clinically beneficial patient response to treatment with an ErbB1 inhibitor, wherein the ErbB1 inhibitor is erlotinib, cetuximab, or gefitinib ~~interacts with an ErbB1 receptor.~~

32.-34. (Canceled)

35. (Previously presented) The method of claim 31 wherein said sample is a tissue sample.

36. (Previously presented) The method of claim 35 wherein the tissue sample is fixed, paraffin-embedded, or fresh, or frozen.

37. (Previously presented) The method of claim 35 wherein the tissue sample is derived from fine needle, core, or other types of biopsy.

Atty Dkt. No.: GHDX-005

USSN: 10/714,195

38. **(Currently amended)** The method of claim 31 further comprising the step of preparing a report comprising a statement whether the patient is likely to respond to treatment with ~~[[an]]~~ the ErbB1 inhibitor.

39. **(Canceled)**

40. **(Withdrawn)** A method comprising administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing colon cancer and determined to have a normalized level of a laminin gamma 2 (LAMC2) RNA transcript that indicates that the patient will likely respond to treatment with an ErbB1 inhibitor.

41. **(Previously presented)** The method of claim 31 wherein the level of the LAMC2 RNA transcript is determined using an array comprising polynucleotides hybridizing to a LAMC2 gene immobilized on a solid surface.

42. **(Previously presented)** The method of claim 41 wherein said polynucleotides are cDNAs.

43. **(Previously presented)** The method of claim 42 wherein said cDNAs are about 500 to about 5000 bases.

44. **(Previously presented)** The method of claim 41 wherein said polynucleotides are oligonucleotides.

45. **(Previously presented)** The method of claim 44 wherein said oligonucleotides are about 20 to 80 bases long.

46. **(Previously presented)** The method of claim 45 wherein the array comprises about 330,000 oligonucleotides.

47. **(Previously presented)** The method of claim 41 wherein said solid surface is glass.

Atty Dkt. No.: GHDX-005
USSN: 10/714,195

48.-50. (Canceled)

51. (Previously presented) The method of claim 35, wherein RNA is isolated from colon cancer cells present in a fixed, paraffin-embedded tissue by a procedure comprising:

- (a) incubating one or more sections of said fixed, paraffin-embedded tissue at a temperature of about 56 °C to 70 °C in a lysis buffer, in the presence of a protease, without prior dewaxing, to form a lysis solution;
- (b) cooling the lysis solution to a temperature where the paraffin solidifies; and
- (c) isolating the RNA from said cooled lysis solution.

52. (Previously presented) The method of claim 31 further comprising the use of a kit comprising one or more of (1) extraction buffer/reagents for extracting mRNA from a sample and protocol; (2) reverse transcription buffer/reagents and protocol; and (3) qPCR buffer/reagents and protocol suitable for performing the method of claim 31.

53.-58. (Canceled)

59. (Previously presented) The method of claim 41, wherein said polynucleotides comprise modified and unmodified polynucleotides.

60. (Currently amended) The method of claim 31, further comprising determining the normalized level of one or more predictive RNA transcripts in said sample, wherein the predictive RNA transcript is the transcript of one or more genes selected from the group consisting of: ~~Bak; Bclx; BRAF; BRK; Cad17; CCND3; CCNE1; CCNE2; CD105; CD9; COX2; DIABLO; ErbB3; EREG; FRP1; GUS; HER2; HGF; ID1; ITGB3; PTPD1; RPLP0; STK15; SURV; TERC; TGFBR2; TITF1; XIAP; CA9; CD134; CD44E; CD44v3; CD44v6; CDC25B; CGA; DR5; GRO1; KRT17; P14ARF; PDGFB; and PLAUR; PPARG; RASSF1; RIZ1; Src; TFRC and UPA~~, wherein an increased normalized level of the predictive RNA transcript of one or more of CA9; CD134; ~~CD44E; CD44v3; CD44v6; CDC25B; CGA;~~ DR5; ~~GRO1;~~ KRT17; P14ARF; ~~PDGFB; and~~ PLAUR; PPARG; RASSF1; RIZ1; Src; TFRC and UPA, indicates that the patient will show a decreased likelihood of response to treatment with an ErbB1 inhibitor, and an increased normalized level of the predictive RNA transcript of one or more of ~~Bak; Bclx; BRAF; BRK; Cad17; CCND3; CCNE1; CCNE2; CD105; CD9; COX2; DIABLO; ErbB3; EREG;~~

Atty Dkt. No.: GHDX-005

USSN: 10/714,195

~~FRP1; GUS; HER2; HGF; ID1; ITGB3; PTPD1; RPLPO; STK15; SURV; TERC; TGFBR2; and~~
~~TITF1; and XIAP~~ indicates that the patient will show an increased likelihood of response to treatment with an ErbB1 inhibitor.

61. (Canceled)

62. **(Currently amended)** The method of claim 31, further comprising determining the normalized level of a predictive RNA transcript of ~~Krt17~~ KRT17 in the sample.

63. (Canceled)

64. **(Withdrawn)** A method comprising administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing cancer and has been determined to have a normalized level of a laminin gamma 2 RNA transcript that indicates that the patient will likely respond to treatment with an ErbB1 inhibitor.

65. (Canceled).